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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,192	03/11/2004	Richard O. Snyder	5853-258-1CON	5141
7590	03/25/2005		EXAMINER	
Akerman Senterfitt Suite #400 222 Lakeview Avenue West Palm Beach, FL 33401-6183			GUZO, DAVID	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/798,192	SNYDER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 21 June 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-28 is/are rejected.
- 7) Claim(s) 29-36 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 11 March 2004 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>9/20/04</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

### **Detailed Action**

#### **Priority**

This application is claiming the benefit of a prior filed nonprovisional application under 35 U.S.C. 120, 121, or 365(c). C dependency between the current application and the prior application is required. Applicants claim benefit of parent application 10/456,423, filed 6/5/03. The 10/456,423 application was abandoned as of **2/17/04**. The filing date of the instant application is **3/11/04**. The chain of continuity between the parent and the instant case is therefore broken and applicants are not entitled to benefit of the 10/456,423 application or the 60/385,864 provisional application. Priority for the claimed invention is granted back to the filing date of the instant application (3/11/04).

#### **Claim Objections**

Claims 29-36 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims 29-36 have not been further treated on the merits.

#### **35 USC 102 Rejections**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Gao et al.

Applicants claim a nucleic acid molecule comprising: (A) a first nucleotide sequence encoding an AAV Rep (i.e. rep 52 and/or rep78) protein of a first serotype; (B) a second nucleotide sequence encoding an AAV Cap protein (composed of VP1, VP2 and VP3) of a second serotype; the second serotype being different from the first serotype; and (C) a third nucleotide sequence encoding a transcription product having at least one Adenoviral helper function (such as E4, E1, E2a, etc.) and wherein the components are under control of expression control sequences. Applicants also recite that the rep protein sequences can be under control of the AAV p5 or p19 promoters and that the cap gene be under control of the p40 promoter, that the nucleic acid sequence contain a selectable marker (antibiotic resistance or GFP) and a mammalian cell containing said nucleic acid. Applicants also claim a AAV based vector in addition to the construct of claim 1 which comprises AAV ITRs (which can be from AAV2) flanking a second nucleic acid sequence which encodes a protein selectable marker (GFP).

Gao et al. (US 2005/0014262, published 01/20/2005, priority to 12/17/2001, see whole document, particularly paragraphs [0040]-[0052]; [0057]-[0063]; [0066]; [0069]; [0073]; [0076]; [0080]-[0084]; [0121]; [0124]) recites a nucleic acid molecule comprising: (A) a first nucleotide sequence encoding an AAV Rep (i.e. rep 52 and/or rep78) protein

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of a first serotype; (B) a second nucleotide sequence encoding an AAV Cap protein (composed of VP1, VP2 and VP3) of a second serotype; the second serotype being different from the first serotype (i.e. the cap gene can be from AAV1, AAV2, AAV5, etc. while the rep gene can be from any of the other different AAV serotypes); and (C) a third nucleotide sequence encoding a transcription product having at least one Adenoviral helper function (such as E4, E1, E2a, etc.) and wherein the components are under control of expression control sequences. Gao et al. also recite that the rep protein sequences can be under control of the AAV p5 or p19 promoters and that the cap gene be under control of the p40 promoter, that the nucleic acid sequence contain a selectable marker (antibiotic resistance or GFP) and a mammalian cell containing said nucleic acid. Gao et al. recite that the above elements for generation of recombinant AAV particles can be on one nucleic acid molecule or the minigene comprising AAV2 ITRs flanking a transgene (which can be a selectable marker such as GFP) can be on a separate molecule. Gao et al. therefore teaches the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7 and 9-27 are rejected under 35 U.S.C. 102(e) and (a) as being anticipated by Fraites et al.

Applicants' invention is as described above.

Fraites et al. (US 2003/0223966, published 12/4/2003, effective filing date of 4/30/2002, see whole document, particularly Fig. 6; paragraphs [0019]-[0020], [0043]-[0046], [0062]-[0064], [0097]) teaches vector pXYZ1 which comprises sequences encoding the rep genes (rep52 and rep78) from AAV2 and the cap gene (VP1-VP3) from AAV1 as well as the adenoviral helper genes required for production of rAAV virions wherein the rep genes are under control of the p5 and p19 promoters and the cap gene is under control of the p40 promoter. The vector backbone for pXYZ1 contains sequences encoding ampicillin resistance as a selectable marker. Fraites et al. also teaches mammalian cells containing the vector as well as AAV2 vectors (i.e. AAV ITRs) comprising a transgene to be expressed wherein the transgene can be a marker. Fraites et al. therefore teaches the claimed invention.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Zolotukhin et al.

Applicants' invention is as described above.

Zolotukhin et al. (Methods, Oct. 2002, Vol. 28, pp. 158-167, see whole article, particularly the Abstract, Fig. 1, the first four paragraphs in the "Methods" section, the first paragraph on p. 161, pp. 163-164) essentially discloses the same data as presented in the instant application. Since priority was not granted to the parent applications in this case because of a break in the chain of continuity, this reference is prior art against the instant claims.

### **35 USC 112, 2<sup>nd</sup> Paragraph Rejections**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 (and dependent claims) are vague in that it recites a "second nucleic acid" to be expressed interposed between AAV ITRs. However, claim 22 is ultimately

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dependent upon claim 1, wherein claim 1 recites a "second nucleotide sequence" encoding a cap protein. It is unclear if the second nucleic acid recited in claim 22 can be the same as the "second" nucleotide sequence recited in claim 1. It is unclear if the second nucleic acid recited in claim 22 is a separate molecule from the nucleic acid molecule of claim 1 or instead recites sequences contained in the nucleic acid molecule of claim 1.

Claim 23 is vague in that there are two "second" nucleic acids recited in the claims from which claim 23 depends and it is unclear which is being referred to.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.  
For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo  
March 6, 2005

  
DAVID GUZO  
PRIMARY EXAMINER